## **Complete Summary**

#### **GUIDELINE TITLE**

Lung cancer prevention: the guidelines.

BIBLIOGRAPHIC SOURCE(S)

Dragnev KH, Stover D, Dmitrovsky E. Lung cancer prevention: the guidelines. Chest 2003 Jan;123(1 Suppl):60S-71S. [81 references] PubMed

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
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CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

## **SCOPE**

## DISEASE/CONDITION(S)

Lung cancer

**GUIDELINE CATEGORY** 

Prevention

CLINICAL SPECIALTY

Family Practice Internal Medicine Oncology Pulmonary Medicine

INTENDED USERS

**Physicians** 

GUIDELINE OBJECTIVE(S)

To provide clinically relevant, evidence-based guidelines for lung cancer prevention

#### TARGET POPULATION

- General population (for smoking prevention)
- Individuals at risk for the development of lung cancer

## INTERVENTIONS AND PRACTICES CONSIDERED

School-based and community-based smoking prevention

- 1. "Life skills training"
- 2. Antismoking campaigns
- 3. Tobacco excise taxes
- 4. Restrictions on smoking in the workplace

## Smoking cessation

- 1. Smokers identified and advised to quit smoking
- 2. Current smokers provided with pharmacotherapy, psychosocial treatment, and behavioral modification therapies as indicated

Chemoprevention (Note: all of these chemopreventive agents are considered but none are recommended outside of a clinical trial)

- 1. Beta-carotene
- 2. Alpha-tocopherol (vitamin E)
- 3. Retinol (vitamin A)
- 4. Aspirin
- 5. Retinoids (i.e., oral isotretinoin)
- 6. Retinol palmitate
- 7. N-acetylcysteine
- 8. Selenium

## MAJOR OUTCOMES CONSIDERED

- Lung cancer incidence
- Smoking rates

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Overview

As a first step in identifying the evidence for each topic, the guideline developers sought existing evidence syntheses including guidelines, systematic reviews, and meta-analyses. They searched computerized bibliographic databases including MEDLINE, Cancerlit, CINAHL and HealthStar, the Cochrane Collaboration Database of Abstracts of Reviews of Effectiveness, the National Guideline Clearinghouse, and the National Cancer Institute Physician Data Query database. Computerized searches through July 2001 used the MeSH terms lung neoplasms (exploded) and bronchial neoplasms or text searches for lung cancer combined with review articles, practice guidelines, guidelines, and meta-analyses. They also searched and included studies from the reference lists of review articles, and queried experts in the field. An international search was conducted of Web sites of provider organizations that were likely to have developed guidelines. Abstracts of candidate English language articles were reviewed by two physicians (one with methodological expertise and one with content area expertise) and a subset was selected for review in full text. Full-text articles were reviewed again by two physicians to determine whether they were original publications of a synthesis and were pertinent to at least one of the topics of the guideline. Articles described as practice guidelines, systematic reviews, or meta-analyses were included, as were review articles that included a "Methods" section. Included articles were classified according to topic.

Strategy specific for lung cancer prevention

Duke University, supported by a contract from the American College of Chest Physicians, searched for phase III studies of putative chemopreventive agents used for primary, secondary, or tertiary prevention in which the primary end point was lung cancer incidence. Duke researchers conducted computerized searches of the MEDLINE bibliographic database from 1966 to July 2001, the HealthStar database, and the Cochrane Library. They searched using the terms lung neoplasm, prevention and control and smoking, prevention and control, along with terms to identify randomized controlled trials (RCTs), systematic reviews, meta-analyses, and practice guidelines. In addition, the reference lists of included studies, practice guidelines, systematic reviews, and meta-analyses were searched.

For chemoprevention studies, the Duke researchers considered only RCTs with lung cancer incidence as an end point. For studies of smoking avoidance or cessation, they selected systematic reviews and meta-analyses, and they searched for individual RCTs only where high-quality and current reviews and meta-analyses were not available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The USPSTF scheme offers general guidelines to assign one of the following grades of evidence: good, fair, or poor. In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between. In addition to the strength of the study design, however, study quality also was considered. The USPSTF approach considers well-recognized criteria in rating the quality of individual studies for a variety of different types of study design (e.g., diagnostic accuracy studies and case-control studies). The thresholds for distinguishing good vs fair and fair vs poor evidence are not explicit but are left to the judgment of panelists, reviewers, and members of the executive committee.

Assessment of the Scope and Quality of Clinical Practice Guidelines

Clinical practice guidelines identified from the systematic search were evaluated by at least four reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each writing committee received a comprehensive list of existing systematic reviews and meta-analyses as well as guidelines published by other groups. In addition, for five key topics (prevention, screening, diagnosis, and staging [invasive and noninvasive], new systematic reviews were undertaken [see "Description of Methods Used to Collect the Evidence" and "Description of Methods Used to Analyze the Evidence" fields]). For all other topics, writing committees were responsible for identifying and interpreting studies that were not otherwise covered in existing syntheses or guidelines.

The guidelines developed by the writing committee were distributed to the entire expert panel, and comments were solicited in advance of a meeting. During the meeting, proposed recommendations were reviewed, discussed, and voted on by the entire panel. Approval required consensus, which was defined as an overwhelming majority approval. Differences of opinion were accommodated by revising the proposed recommendation, the rationale, or the grade until consensus could be reached. The evidence supporting each recommendation was

summarized, and recommendations were graded as described. The assessments of level of evidence, net benefit, and grade of recommendation were reviewed by the executive committee.

#### Values

The panel considered data on functional status, quality and length of life, tolerability of treatment, and relief of symptoms in formulating guideline recommendations. Cost was not explicitly considered in the guideline development process. Data on these outcomes were informally weighted, without the use of explicit decision analysis or other modeling. The values placed on types of outcomes varied with clinical scenarios. For example, in some situations they considered life expectancy, such as the effects of early detection. In other situations they weighted quality of life more heavily, such as in palliative care and in interpreting small increases in life expectancy with chemotherapy for stage IV disease.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The guideline developer´s grading scheme is a modification of the US Preventive Services Task Force (USPSTF) grades to allow recommendations for a service when (1) evidence is poor, (2) the assessment of the net benefit is moderate to high, and (3) there is consensus among the expert panel to recommend it. This change was necessary because, unlike preventive services (i.e., the routine offering of tests or treatments to well people) in which the burden of proof is high, clinical decisions about the treatment of patients with lung cancer often must be based on an interpretation of the available evidence, even if it is of poor quality. This adaptation distinguished between interventions with poor evidence for which there is consensus (grade C) and interventions with poor evidence for which there is not consensus (grade I).

#### Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc).

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that [the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

#### Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically important.

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After extensive review within the expert panel and executive committee, the guidelines were reviewed and approved by the American College of Chest Physicians (ACCP) Health and Science Policy Committee and then by the American College of Chest Physicians Board of Regents.

## RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Each recommendation is rated based on the levels of evidence (good, fair, poor), net benefit (substantial, moderate, small/weak, none/negative), and the grades of the recommendations (A, B, C, D, I). Definitions are presented at the end of the "Major Recommendations" field.

- 1. For all individuals, smoking prevention should be strongly encouraged to decrease the risk of lung cancer. Level of evidence, good; benefit, substantial; grade of recommendation, A
- 2. For all individuals, school-based and community-based interventions that are aimed at reducing tobacco exposure should be recommended, including a "life skills training" approach that is aimed at reducing tobacco, alcohol, and illicit drug use, campaigns with brief recurring antismoking messages, high tobacco excise taxes, and restrictions on smoking in the workplace. Level of evidence, good; benefit, substantial; grade of recommendation, A
- 3. Smokers should be identified as smoking cessation reduces the risk of lung cancer. Level of evidence, good; benefit, substantial; grade of recommendation. A
- 4. Current smokers should be advised to quit smoking, and, when appropriate, clinicians should prescribe and monitor pharmacotherapy. Individuals who smoke and want to quit also should have access to psychosocial treatment and behavioral modification therapies as indicated. There is sufficient-to-strong evidence that indicates these practices will help to increase long-term smoking abstinence rates. Level of evidence, good; benefit, substantial; grade of recommendation, A
- 5. Individuals who are at risk for lung cancer and were treated with beta-carotene, retinol, isotretinoin, or N-acetyl-cysteine for lung cancer prevention did not experience clinical benefit. There is also evidence that the use of beta-carotene and isotretinoin for lung cancer chemoprevention in high-risk individuals may increase the risk for lung cancer, especially in individuals who continue to smoke. These agents should not be used outside of a clinical trial for primary, secondary, or tertiary lung cancer prevention. Level of evidence, good; benefit, harmful; grade of recommendation, D
- 6. For individuals at risk for lung cancer and for patients with a history of lung cancer there are not yet sufficient data to recommend the use of any agent either alone or in combination for primary, secondary, or tertiary lung cancer chemoprevention outside of a clinical trial. Level of evidence, insufficient; benefit, lacking data; grade of recommendation, I

## Definitions:

#### Levels of Evidence

In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between.

#### Grades of Recommendations

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that [the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the

service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

#### Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important

degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically

important.

## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS.

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Of the many strategies that might be considered for reducing lung-specific cancer risks, only smoking prevention and cessation has been shown to reduce lung cancer risk. Although the focus of this guideline is on the chemoprevention of lung cancer, it is primary prevention (i.e., smoking prevention) that should be a major

focus within our society including local communities, schools from kindergarten through college, and among persons in the medical profession. Strategies that have been the most successful in preventing children from starting to smoke include all-grade inclusive school programs that emphasize a "life skills training approach," the use of brief recurring antismoking messages that point out the positive aspects of being nicotine-free, and the enforcement of high excise taxes on tobacco products. For current smokers, there is strong evidence that brief recurring physician advice significantly increases long-term smoking abstinence rates. Clinician-based approaches should always include the routine identification of tobacco users, which in turn increases the rate of clinician intervention with patients who smoke.

POTENTIAL HARMS

Not stated

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

- 1. The American College of Chest Physicians (ACCP) is developing a set of PowerPoint slide presentations for physicians to download and use for physician and allied health practitioners education programs.
- 2. The ACCP is developing a Quick Reference Guide (QRG) in print and PDA formats for easy reference.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Dragnev KH, Stover D, Dmitrovsky E. Lung cancer prevention: the guidelines. Chest 2003 Jan;123(1 Suppl):60S-71S. [81 references] PubMed

**ADAPTATION** 

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

## GUI DELI NE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

#### GUI DELI NE DEVELOPER COMMENT

The guideline development panel was composed of members and nonmembers of the American College of Chest Physicians (ACCP) who were known to have expertise in various areas of lung cancer management and care, representing multiple specialties from the following 13 national and international medical associations:

- Alliance for Lung Cancer Advocacy, Support, and Education (a patient support group)
- American Association for Bronchology
- American Cancer Society
- American College of Physicians
- American College of Surgeons Oncology Group
- American Society of Clinical Oncology
- American Society for Therapeutic Radiology and Oncology
- American Thoracic Society
- Association of Community Cancer Centers
- Canadian Thoracic Society
- National Comprehensive Cancer Network
- Oncology Nursing Society
- Society of Thoracic Surgeons

The specialties included pulmonary/respiratory medicine, critical care, medical oncology, thoracic surgery, radiation oncology, epidemiology, law, and medical ethics.

#### SOURCE(S) OF FUNDING

Funding for both the evidence reviews and guideline development was provided through an unrestricted educational grant from Bristol-Myers Squibb, which had no other role in the evidence review or guideline development process or content.

#### **GUIDELINE COMMITTEE**

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Konstantin H. Dragnev, MD; Diane Stover, MD, FCCP; Ethan Dmitrovsky, MD

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Information about potential conflicts of interest were collected from each member of the expert panel or writing committee at the time of their nomination in accordance with the policy of the American College of Chest Physicians. Information on conflicts of interest for each panelist is listed in the guideline.

#### **GUI DELI NE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available to subscribers of <u>Chest - The Cardiopulmonary and</u> Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

#### AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

## **Evidence Summary:**

• Kelley MJ, McCrory DC. Prevention of lung cancer: summary of published evidence. Chest 2003 Jan; 123(1 Suppl): 50S-59S.

## Background Articles:

- Alberts WM. Lung cancer guidelines. Introduction. Chest 2003 Jan; 123(1 Suppl): 1S-2S.
- McCrory DC, Colice GL, Lewis SZ, Alberts WM, Parker S. Overview of methodology for lung cancer evidence review and guideline development. Chest 2003 Jan; 123(1 Suppl): 3S-6S.
- Harpole LH, Kelley MJ, Schreiber G, Toloza EM, Kolimaga J, McCrory DC. Assessment of the scope and quality of clinical practice guidelines in lung cancer. Chest 2003 Jan; 123(1 Suppl): 7S-20S.
- Alberg AJ, Samet JM. Epidemiology of lung cancer. Chest 2003 Jan; 123(1 Suppl): 21S-49S.

Electronic copies: Available to subscribers of <u>Chest - The Cardiopulmonary and Critical Care Journal</u>.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

#### PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 30, 2003. The information was verified by the guideline developer on July 25, 2003.

## COPYRIGHT STATEMENT

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